

Appl. No. 10/802,381  
Reply to Office Action of September 16, 2004

Remarks

Introduction

Claims 1-30 were pending. By way of this response, claims 5, 11, 15, 23, 25, 27, and 30 have been amended, and claim 21 has been cancelled without prejudice. Support for the amendments to the claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 1-20 and 22-30 are currently pending.

Status of the Claims & Support for Amendments

Claims 1-20 and 22-30 are pending. Claim 21 has been cancelled. By way of this response, claims 5, 11, 15, 23, 27, and 30 have been amended.

Claim 5 has been amended by replacing "administering" with --intramuscularly administering-- and by inserting --to cause paralysis of a depressor anguli oris (DAO) muscle-- after "human patient. Support for the amendments to claim 5 can be found at column 2, lines 38-48.

Claim 11 has been amended by replacing "the amount of Botulinum toxin is less than about 4 units" with --the botulinum toxin is injected into the DAO muscle, and further comprising injecting an obicularis oris muscle with a total dose of botulinum toxin in the order of 4 units for the entire upper lip--. Support for the amendments to claim 11 can be found at column 4, lines 1-11.

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Claim 15 has been amended by inserting --in conjunction with a treatment of Marionette lines and sad mouth by injection of a botulinum toxin into a depressor anguli oris muscle, the total amount of the botulinum toxin being on the order of 4 Units for the entire upper lip-- after "upper lip wrinkles" on line 5 of claim 15. Support for the amendments to claim 15 can be found at column 4, lines 1-11.

Claim 21 has been cancelled.

Claim 23 has been amended by inserting --intramuscularly-- before "administering" and by replacing "a depressor anguli oris" with --each depressor anguli oris--. Support for the amendments to claim 23 can be found at column 4, lines 1-26.

Claim 25 has been amended by replacing "administered" with --injected--. Support for the amendment to claim 25 can be found at column 4, lines 1-11.

Claim 27 has been amended by replacing "a depressor anguli oris" with --each depressor anguli oris--. Support for the amendments to claim 27 can be found at column 4, lines 22-26.

#### Item 2

The Office Action indicates that the original patent or a statement as to the loss or inaccessibility of the original patent must be received before the above-identified reissue application can be allowed.

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Applicant intends to submit the original patent when the application is otherwise in condition for allowance.

Item 3

Applicant acknowledges its obligation to timely apprise the USPTO of any prior or concurrent proceeding in which the original patent (U.S. Patent No. 6,358,917) is or was involved.

Applicant notes that the Office Action refers to U.S. Patent No. 5,583,114 (Barrows et al., and entitled Adhesive Sealant Composition). Applicant assumes this was an error, and requests confirmation of same.

Items 4-5 - Rejections Under 35 U.S.C. §§ 251 and 112, first paragraph

Claims 1-30 have been rejected under 35 U.S.C. § 251 as allegedly containing new matter. In particular, claims 5-11, 13, 14, and 23-25 have been rejected because the claims do not specifically require injection of botulinum toxin. Claims 5-11, 13, and 14 have been rejected because the claims do not require that the botulinum toxin be injected into the depressor anguli oris (DAO) muscle. Claim 11 has been rejected because the amount of botulinum toxin recited in the claim extends below about 2 units. Claims 15-22 and 26 have been rejected because the claims do not require that the treatment be in conjunction with treatment of Marionette lines and sad mouth by injection of botulinum toxin into the DAO muscle. Claims 15-20 and 22-26 have been rejected because they are not limited to the injection of any particular amounts of botulinum toxin. Claims 23-25 have

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been rejected because the claims do not require that the botulinum toxin be injected into both DAO muscles. Claim 30 has been rejected because the claim is not limited to the lip area of the patient's mouth.

Claims 5-11 and 13-30 have been rejected under 35 U.S.C. § 112, first paragraph for lacking a written description for the subject matter identified above regarding the rejections under 35 U.S.C. § 251.

As a preliminary matter, applicant notes that claims 1-4 have been included in the rejection. Claims 1-4 correspond to the original issued claims, and claims 1-4 have not been specifically rejected. Applicant assumes that the Examiner intended to reject claims 5-30 under 35 U.S.C. § 251. Applicant requests confirmation that claims 1-4 were not rejected under this section.

As to claims 5-11, 13, 14, and 23-25 being rejected for not being limited to injection of botulinum toxin, applicant traverses the rejection. However, applicant has amended claims 5 and 23 to make more clear that the botulinum toxin is intramuscularly administered, and has amended claim 25 to make more clear that the botulinum toxin is injected. Applicant traverses the rejection as it relates to the present claims.

Applicant submits the Office Action is in error when indicating that the original disclosure is limited to injection of botulinum toxin and does not disclose administration in general.

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For example, the abstract and column 2, lines 38-41 state that "This invention provides the use of *Botulinum* toxin (BTX) to cause paralysis of a depressor anguli oris (DAO) musculature in a patient to alleviate downturn corners of the patient's mouth." (emphasis added). The Summary of the Invention goes further to state that "[t]his invention provides [a] method of alleviating downturn of corners of a patient's mouth ... (column 2, lines 42-48; emphasis added). In addition, the Detailed Description states that "[t]his invention provides a successful treatment of Marionette lines and "sad mouth" by BTX injection into the DAO." (column 4, lines 1-3; emphasis added).

In view of the foregoing, it is clear that the original disclosure contemplates and describes more general use of botulinum toxin, rather than just injection of botulinum toxin. For example, the original disclosure specifically states that the invention provides the use of botulinum toxin to cause paralysis of the DAO musculature. The original disclosure then provides a detailed description of one embodiment of the invention, which one embodiment is a method which comprises injection of botulinum toxin into a DAO muscle.

Applicant submits that the original disclosure employs the term "a method" in referring to the specific embodiment of injection of botulinum toxin. The word "use" relating to botulinum toxin to cause paralysis of a DAO musculature as noted above clearly indicates that applicant was describing the use or administration of botulinum toxin in general to cause paralysis of a DAO muscle. Therefore, applicant submits that intramuscularly administering a botulinum toxin, as recited in

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claim 5 and claim 23 in particular, is properly described in the original disclosure and does not constitute new matter.

Similarly, applicant submits that the original disclosure is not limited to injection of botulinum toxin into the DAO muscle. As discussed above, injection of botulinum toxin into the DAO muscle is a step of one embodiment of the methods set forth in the original disclosure, but does not limit the disclosure of the more general aspects of the invention. Simply put, when the original disclosure is read as a whole, it is clear that applicant's invention is directed to the use of a botulinum toxin to cause paralysis of the DAO musculature. Thus, the invention is not limited to a specific site of administration of botulinum toxin. The invention is directed to administration of a botulinum toxin to a region in proximity to each of the corners of a mouth of a human patient to cause paralysis of the DAO musculature. For example, FIG. 2 specifically shows regions 6 which correspond to the general location on the patient's skin where botulinum toxin can be administered. In embodiments where injection of botulinum toxin is employed, the botulinum toxin can be injected at the sites marked with "X" in FIG. 2. Therefore, applicant submits that the original disclosure is not limited to injection of botulinum toxin into a DAO muscle, and that the present claims are properly described in the original disclosure and do not contain new matter.

Applicant submits that the rejection of claim 11 for encompassing an amount of botulinum toxin less than about 2 units is moot in view of the amendments to claim 11, as set forth above.

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Applicant submits that the rejection of claims 15-22 and 26 for not indicating that the upper lip wrinkle treatment is in conjunction with treating Marionette lines and sad mouth by injection of botulinum toxin into the DAO muscle is moot in view of the amendments to claim 15, as set forth above.

Applicant submits that the rejection of claims 15-20 and 22-26 for not reciting any particular amounts of botulinum toxin is moot in view of the amendments to claim 15. Claim 15 recites that the total amount of the botulinum toxin is on the order of 4 Units for the entire upper lip.

Applicant submits that the amendments to claims 23 and 27 render the rejections of claims 23-25 and 27-30 moot. Claims 23 and 27 now clearly indicate that the botulinum toxin is administered to each DAO muscle adjacent a corner of the mouth.

Applicant submits that the amendments to claim 30 render the rejection of claim 30 moot. Claim 30 more clearly recites that the method comprises a step of injecting a botulinum toxin to an upper lip region located above the patient's mouth.

In view of the above, applicant submits that the rejections of claims 5-30 under 35 U.S.C. § 251 and § 112, first paragraph have been overcome, and applicant respectfully requests that such rejections be withdrawn.

Items 7-10 - Rejections under 35 U.S.C. §§ 102 and 103

Claims 27 and 28 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bikhazi et al. (1997). Claims

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15-22 and 26 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Carruthers et al. (1999) in view of Klein (1999). Claims 15 and 16 have been rejected under 35 U.S.C. § 102(b) as allegedly being obvious over Sabbaugh (1998). Claims 17-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Sabbaugh.

The claims have been amended as set forth above. Applicant submits that the rejections under 35 U.S.C. §§ 102 and 103 are moot in view of the amendments to the claims. Applicant traverses the rejections as they relate to the present claims.

Applicant submits that Bikhazi et al. does not disclose, teach, or suggest the present invention. For example, Bikhazi et al. does not disclose, teach, or even suggest a method of alleviating downturn of corners of a patient's mouth which comprises injecting into each DAO muscle adjacent each corner of the mouth, a quantity of botulinum toxin sufficient to cause paralysis of the DAO, as recited in present claim 27.

Bikhazi et al. discloses unilateral administration of a botulinum toxin to patients with unilateral facial paralysis. The botulinum toxin is administered to alleviate the asymmetric features of the patients with unilateral paralysis. Since Bikhazi et al. does not disclose, teach, or even suggest injecting each DAO muscle (e.g., the DAO muscles on both sides of the mouth), Bikhazi et al. does not anticipate or make obvious the present claims, and claims 27 and 28 in particular.

Claim 15 has been amended to make more clear that the treatment of severe upper lip wrinkles is in conjunction with a



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treatment of Marionette lines and sad mouth by injection of a botulinum toxin into a DAO muscle. Applicant submits that the Declaration under 37 CFR 1.132 by Carruthers et al. filed on June 11, 2001 during the prosecution of the parent application is sufficient to show that the Carruthers et al. reference is not available as prior art under 35 U.S.C. § 102(a) with respect to the amended claim. As indicated in the Office Action, the Examiner has reviewed the Declaration. The Declaration states that treatment of Marionette lines by injection of BOTOX into the DAO originated from the joint work and invention of Jean D.A. Carruthers and Alastair Carruthers, the present inventors. In view of the above, applicant submits the rejection of claims 15-22 and 26 based on Carruthers et al. in view of Klein has been overcome.

Applicant disagrees that Sabbaugh discloses injecting botulinum toxin to alleviate severe upper lip wrinkles, as recited in claim 15. Sabbaugh discloses injection of botulinum toxin to treat perioral rhytids and smoker's lines. Applicant submits that Sabbaugh does not disclose, teach, or even suggest alleviating severe upper lip wrinkles, let alone doing so in conjunction with a treatment of Marionette lines and sad mouth, as recited in claim 15. Therefore, applicant submits that Sabbaugh does not anticipate the present claims, and claims 15 and 16 in particular, under 35 U.S.C. § 102.

In addition, since Sabbaugh does not disclose, teach, or even suggest the invention of claim 15, applicant submits that Sabbaugh does not disclose, teach, or even suggest the inventions of claims 17-21, which claims are dependent from claim 15.

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In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In view of the above, applicant submits that the present claims, that is claims 1-20 and 22-30, are not anticipated by, and are unobvious from and patentable over the prior art, including Bakhazi et al., Carruthers et al., Klein, and Sabbaugh, taken alone or in any combination under 35 U.S.C. §§ 102 and 103.

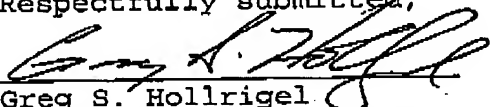
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Conclusion

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. §§ 251 and 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-20 and 22-30 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 1/18/05

Respectfully submitted,

  
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